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(Article begins on next page)

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No Cranberries for Thanksgiving: The Impact of FDA Adverse Publicity

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Abstract

As the primary federal agency responsible for regulating the safety of food, drugs, medical devices, and cosmetics, The Food and Drug Administration (“FDA”) has enormous responsibility. With this responsibility comes power. Through its various enforcement mechanisms, the FDA seeks to protect the health and welfare of Americans. One mechanism the FDA employs involves the use of publicity to warn the public about potentially hazardous products. This adverse publicity^{1, *regardless of*} the accuracy of the information contained therein, can have a disastrous impact on the target of the publicity. At times, it has resulted in significant business losses or even cessation of the business’ operations. Parties harmed by this adverse publicity have turned to the courts, largely unsuccessfully, to recover damages from loss profits and/or to enjoin the FDA from disseminating adverse publicity regarding their products. Courts generally have failed to rule in favor of these plaintiffs. This paper discusses these cases. It begins with a brief overview of the agency’s publicity practice, including the statutory basis, the means through which the agency disseminates this information, and the benefits and disadvantages of the practices. Next, the paper analyzes the case law involving plaintiffs who brought action against the FDA because of adverse publicity, starting with those in which plaintiff have been unsuccessful and then concluding with those in which they have not. This paper concludes with recommendations for ways to balance the needs of the public to be alerted to potential health hazards with the needs of the companies affected by the publicity.

Statutory Authority

The FDA is one of the few federal agencies that have expressed statutory authorization to disseminate information to the public. Section 375(b) of the Federal Food, Drug, & Cosmetic Act (“FDCA”) empowers the FDA to cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations

involving, in the opinion of Secretary, imminent danger to health or gross deception to the consumer.”² Further, this provision authorizes the FDA to collect, report, and illustrate results of FDA investigations.³ The publicity is disseminated through various means including press releases⁴, speeches⁵, the agency’s official magazine, FDA Consumer⁶, and news conferences.

Benefits

The benefits of this publicity are quite obvious. As Gellhorn notes, by disseminating this information, the FDA “serves its most important and accepted function in warning the public of imminent perils to health and safety.”⁷ Additionally, publicity is necessary in light of the limited formal enforcement remedies the FDA has at its disposal. Under the FDCA, the FDA has two major means of removing defective products from the market, injunctions⁸ and seizures⁹, both of which require court approval and can be costly and time-consuming.¹⁰ Further, these measures can prove ineffective if the manufacturer is uncooperative.¹¹

²21 U.S.C. § 375(b). Section 375(a) authorizes the FDA to publish “from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.” This paper does not focus on FDA actions initiated under this provision.

³*See id.*

⁴*See, e.g.*, Food and Drug Administration, *FDA Issues Public Health Advisory on Tysabri, a New Drug for MS*, FDA NEWS (2005) (warning “patients and health care providers about the suspended marketing of Tysabri while the agency and the manufacturer evaluate two serious adverse events reported with its use”), at <http://www.fda.gov/bbs/topics/news/2005/NEW01158.html>

⁵*See, e.g.*, Lester M. Crawford, D.V.M., Ph.D., FDA Acting Commissioner, Remarks before Pharmaceutical Education Associates (March 22, 2005) (stating that the FDA issued a warning letter to drug manufacturer Novartis regarding the manufacturer’s promotional claims that its product is effective in treating patients with type 2 diabetes and hypertension to preserve renal function”), at <http://www.fda.gov/oc/speeches/2005/pea0322.html>.

⁶*See, e.g.*, *Lead Contamination in Candy*, FDA CONSUMER (July-August 2004) (warning that “some Mexican candy sold in the United States has been associated with lead contamination, and that the FDA is advising that it would be prudent to not allow children to eat these products”), 2004 WLNR 11481159, available at http://www.fda.gov/fdac/departs/2004/404_upd.html#lead.

⁷Ernest Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380, 1407 (1973)

⁸28 U.S.C. §332.

⁹*See* U.S.C. § 334 which provides in part that “any article of food, drug, or cosmetic that is adulterated or misbranded. . . shall be liable to be proceeded against. . . on libel of information and condemned in any district court of the U.S.”

¹⁰*See* Gellhorn, *supra* note 7; *See also* Recall Procedures, FDA Regulatory Procedures Manual March 2004 (stating that “[r]ecalls afford equal consumer protection but generally are more efficient and timely than formal administrative or civil actions, especially when the product has been widely distributed”), available at http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch7.pdf.

¹¹*Id.*

Gellhorn argues that the because the FDA does not have the authority on its own to detain products pending investigation, the FDA has used its publicity power in conjunction with its practice of “voluntary recalls” not only to warn the public but also as a means of ensuring compliance.¹²

Negative FDA publicity from the FDA can be fatal to the subject of the publicity. The targeted parties are virtually powerless in stopping the message. Adverse publicity can lead to liability suits, trade rejection and returns, brand name hostility, and physician fear of malpractice claims from using a publicized drug.¹³ Because of the heavy competition involved with getting products on the market, retailers have little incentive to keep a targeted product on its shelves. For example, a major drug retailer pulled a medical device from its shelves immediately after the FDA issued an alert regarding the device.¹⁴

Critics argue that FDA adverse publicity is used unjustifiably and in circumstances outside the prescribed statutory scope.¹⁵ The statute provides that adverse publicity is warranted in instances of imminent danger and gross deception, however, some argue that the FDA does not limit its publicity to these circumstances. For example, the FDA issued a Class III recall of approximately 15,000 candy bars. The FDA defines Class III recalls as those that are “routine situation[s] in which the consequences to life are remote or are non-existent.”¹⁶ Although the company recalled the product, the FDA published this information in sources including the Wall Street Journal.¹⁷

¹²*Id.* at 1407-8 (arguing that the FDA ensures compliance by threatening seizure, injunction, and the issuance of publicity, with the threat of publicity having the most impact); *see also* John M. Packman, 53 FOOD & DRUG L.J. 437, 439 (stating that when a salmon distributor refused to recall a product contaminated with lysteria, FDA’s parent agency, the Department of Health and Human Services, issued a press release stating that the distributor was uncooperative and refused to recall the product).

¹³Morey, *FDA Publicity Against Consumer Products—Time for Statutory Revitalization?* 30 BUS LAW 165, 167 (1975).

¹⁴*See id.* citing FDA Quarterly Report, First Quarter 1987, at 20 (1987)

¹⁵*See* Richard S. Morey, Publicity as a Regulatory Tool, 30 Food Drug Cosm. L.J. 469, 470 (1975).

¹⁶*Id.*

¹⁷*Id.*

The FDA is not required to notify companies of its intention to issue adverse publicity. Thus, companies often do not have an opportunity to respond to the FDA's concerns. As the following situation illustrates, this is especially problematic when the publicity contains misleading or inaccurate information.

The Cranberry Crisis

During a 1959 pre-Thanksgiving press conference, Arthur Flemming, the then Secretary of Health, Education and Welfare ("HEW") stated that certain Washington- and Oregon-grown cranberries were potentially hazardous because they contained pesticides shown to cause cancer in laboratory rats and that he was not going to eat them at Thanksgiving dinner.¹⁸ Because it was difficult to determine where particular cranberries were grown, this announcement led to almost the complete wipeout of the national cranberry market.¹⁹ This publicity resulted in approximately \$21,500,000 unsold pounds of cranberry.²⁰ Later testing revealed that of the approximately 33,600,000 million pounds of cranberries tested, only 325,800 pounds were found to be contaminated.²¹ Although, even though 99 percent of it was subsequently cleared and approved by the government, the majority of the crop was unsold.²² The government compensated the cranberry growers approximately 9 million dollars for the destroyed market.²³

FTCA

¹⁸See Ernest Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380, 1408 (1973);

¹⁹*Id.*

²⁰*Id.*

²¹*Id.* at -10 (1973); see also Edward Smith, *The Cranberry Scare and Cabinet Immunity*, 16 FOOD DRUG COSM L.J. 209, n3 (1961);

²²*Id.*

²³*Id.*

Other parties have not been as successful as the cranberry growers in their attempt to recover damages due to adverse publicity. Several companies have turned to the courts to recover damages that the company deems resulted from the FDA's adverse publicity. The Federal Torts Claims Act (FTCA)²⁴ has been a significant barrier to these plaintiffs.

As the following cases illustrate, the discretionary function exemption in the FTCA presents a formidable obstacle to plaintiffs seeking compensation from adverse publicity. The FTCA permits negligence and intentional tort suits against government in certain instances.²⁵ The discretionary function exception of the FTCA, however, states that the government retains sovereign immunity with respect to "[a]ny claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, . . . or based upon the exercise or performance . . . on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."²⁶ Courts have interpreted this exception liberally, awarding great deference to the FDA's discretion to issue publicity. Further, the FTCA bars suits against the government arising out of libel and misrepresentation.²⁷

Overcoming the FTCA Hurdle

On March 2, 1989, an anonymous caller contacted the US embassy in Chile claiming that cyanide had been injected in Chilean grapes exported to the US.²⁸ The FDA detained all incoming Chilean fruit while it investigated the claim. Four days later, having found no evidence of poisoning, the FDA announced

²⁴28 U.S.C.A. § 2680(h)

²⁵§1346(b)(1) permits "civil actions on claims against the United States, for money damages . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. 1346(b)(1).

²⁶28 U.S.C. § 2680(a)

²⁷See 28 U.S.C. 2680(h)

²⁸See *Fisher Bros. Sales, Inc. v. U.S.*, 46 F.3d 279, 282 (1995).

that the call was a hoax.²⁹ The embassy received another call stating that the cyanide poisoning was not a hoax. An FDA laboratory in Philadelphia inspected the incoming fruit and concluded that two grapes appeared to have been punctured and that cyanide could have been injected into the grapes.³⁰ An FDA lab in Cincinnati, however, found no evidence of cyanide in the grapes. The FDA Commissioner, faced with the conflicting results, issued an order refusing entry of additional Chilean fruit and issued a press release publicizing the Philadelphia laboratory's findings. The press release also encouraged consumers to destroy fruit in their possession and instructed grocers to remove all Chilean fruit from their shelves.³¹ As a result, a group of Chilean growers and fresh fruit exporters sued the U.S. for 210 million dollars under the FTCA. The suit alleged that the Philadelphia lab technicians were negligent and that the Commissioner issued the order based on this negligence. The plaintiffs' negligence strategy was their attempt to preclude the FDA from asserting the discretionary function exemption. The Third Circuit found for the FDA holding that the process of gathering facts is a part of FDA's discretionary functions, and the communication to the public about risk was a discretionary decision of the FDA Commissioner.³²

²⁹*Id.*

³⁰*Id.* at 282-3.

³¹*Id.* at 283.

³²*Id.* at 288.

A plaintiff seeking to recover due to incorrect adverse publicity can avoid the discretionary function barrier by obtaining a private bill through Congress permitting a waiver of sovereign immunity to bring suit in the Court of Claims.³³ This was the situation in *Mizokami v. US*.³⁴ The plaintiffs were growers and shippers of fresh vegetables.³⁵ In 1962, the FDA inspected samples of plaintiffs' spinach for violations of the FDA. Preliminary tests concluded that some of the spinach was contaminated with heptachlor, a pesticide. The FDA commenced a seizure action against "418 bushels of spinach" on grounds that it was contaminated or adulterated within the meaning of the FDCA. Plaintiffs initiated its own inspection of the spinach which concluded that heptachlor was not present in the tested samples. Plaintiff notified the FDA of these results. After having a sample of the condemned spinach retested using more sensitive means than had been used previously, and finding no presence of the pesticide, the Deputy Commissioner of FDA admitted to plaintiffs that its original conclusion was erroneous. The plaintiffs sought damages of \$543,879.96 asserting negligence and willful misrepresentation.³⁶ The plaintiff's obtained a private bill³⁷ to circumvent the FTCA's bar against suits these claims.³⁸ The court held that the bill waived the sovereign immunity protection and stated that "[t]o hold otherwise would be to presume that Congress passed the bill in question merely to send plaintiffs to this forum for a ritual confirmation of the Neustadt rule and concomitant dismissal of their petition."³⁹ The court further held that the bill concedes liability for the FDA's actions but left it up to the court to determine the appropriate damages and whether there was a causal link between the FDA's actions and the resulting harm.⁴⁰ The court found that plaintiffs' established a sufficient connection between the FDA's actions and the plaintiff's alleged losses and awarded the plaintiffs approximately \$300,000 in damages.⁴¹

The plaintiffs in *Sperling & Schwartz, Inc. v. United States*⁴² also attempted to obtain a private bill to bring suit but were unsuccessful. There, a dish importer sued the FDA after its sales declined subsequent to

⁴²1977 U.S. Cl. Ct. LEXIS 336 (1977).

an FDA press release warning that sales of certain dishes were affected after an FDA press release warned against the use of claimant's dinnerware. The press release stated, in part, that the FDA warned consumers in certain areas to "avoid using a brand of imported English dinnerware after analysis of the product revealed very high levels of leachable lead content..."⁴³ The press release further stated that the FDA began an investigation after learning "that a Baltimore child became ill apparently from eating a fruit preparation stored in [the dinnerware]..."⁴⁴ After the press release, plaintiff initiated a voluntary recall of the products. After discussions with the plaintiff, approximately two months after the initial press release, the FDA issued a second press release indicating that the dinnerware was less hazardous than had been indicated in the previous release.⁴⁵ The press release stated that decals could be a source of leachable lead, but that decal-bearing dinnerware presented a health hazard only if used to store acidic foods or beverages."⁴⁶ The plaintiff alleged that the second press release came too late after the initial one and sought recovery for the losses incurred by the recall. The court denied recovery and recommended that the private bill not be enacted.⁴⁷

Another possible means of avoiding the discretionary function exemption is if the plaintiff can show that the agency's actions did not result from an exercise of its discretion but from a failure to adhere to its own policies. The discretionary function exemption is inoperative if the FDA violated its own regulations. If a plaintiff can show that it sustained injury as a result of the FDA's breach of its duty, the plaintiff can possibly recover because the FDA had no discretion to breach its duty. For example, in *Berkovitz v United States*,⁴⁸ a plaintiff who contracted polio after ingesting the oral polio vaccine sued the FDA for its approval of the vaccine's production and distribution.⁴⁹ The plaintiff alleged that by approving the use of the vaccine,

⁴³*Id.* at 8-9

⁴⁴*Id.*

⁴⁵*Id.* at 10.

⁴⁶*Id.* at 10-11.

⁴⁷*Id.* at 91-2.

⁴⁸486 US 531 (1988).

⁴⁹*Id.* at 533.

the FDA violated its policy regarding the inspection and approval of vaccines.⁵⁰ The Court rejected the government's assertion of the discretionary function exemption holding that the exemption is inapplicable "when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow."⁵¹ In this situation, the Court reasoned, the government official lacks has no discretion to disregard its policy and thus its actions do not involve judgment or choice. Thus, "there is no discretion in the conduct for the discretionary function exception to protect."⁵² Plaintiffs suing for publicity-related losses likely cannot utilize the Berkowitz exception to the discretionary function rule since the holding narrowly applies to the agency's failure to follow specific, prescribed regulations. Although the agency attempted to establish regulations regarding its use of publicity, the FDA does not have specific regulations governing this practice.⁵³

Unconstitutionality of Publicity Provision §375(b)

Some plaintiffs have sought recovery by arguing that §375(b) of the FDCA is an unconstitutional violation of due process. For example, in *Hoxsey Cancer Clinic v Folsom*,⁵⁴ the plaintiff filed suit to enjoin the FDA from disseminating circulars warning the public that the plaintiff's cancer treatment was ineffective in treating internal cancer.⁵⁵ The plaintiff claimed that Section 375(b) was unconstitutional denial of due process as it contains no notice or hearing requirement.⁵⁶ The court rejected this claim stating that by disseminating the circulars, the FDA was not issuing an order, adjudicating rights or issuing directions and thus there was no basis for notice or a hearing.⁵⁷ The court further held that the FDA was merely performing a public duty

⁵⁰*Id.*

⁵¹*Id.* at 536.

⁵²*Id.*

⁵³The FDA published a policy statement on the agency's future use of pretrial publicity. 42 Fed. Reg. 12436 (Mar. 4, 1977)

⁵⁴155 F Supp 376 (DDC 1957), *affd* without opinion, 513 F2d 625 (3d Cir 1975)

⁵⁵*Id.* at 377.

⁵⁶*Id.* at 378

⁵⁷*Id.*

by warning the public and that the challenged statute only expressly authorized the government to do what it was already implicitly permitted to do.⁵⁸

Similarly, in *Ajay Nutrition Foods, Inc v FDA*,⁵⁹ a class of health food distributors sought to enjoin the FDA agency from issuing press releases and public announcements which used the terms “quacks,” “faddists,” and “shotgun mixtures.”⁶⁰ The plaintiffs alleged that the publicity amounted to the deprivation of property without due process and wrongful and unlawful interference with the plaintiffs’ right to conduct business.⁶¹ The plaintiffs sought \$500 million in recovery.⁶² The court rejected the plaintiff’s claim holding that the press releases were statements were within the scope of the privilege afforded to government officials acting in official capacity.

Enjoining Use of Publicity

In *United States v Diapulse Mfg Corp*,⁶³ a drug company sought to enjoin the FDA from issuing public statements related to the FDA’s misbranding action against the company. The statements at issue were a report that contained two pages of reference to the misbranding action and a speech by then FDA Commissioner Goddard delivered to the Congress of Medical Quackery stating, “You probably know of the ‘Diapulse’ case. This device, seized in Atlanta, Georgia, used electrical impulses to supposedly treat arthritis, hypertension, sinusitis, middle ear infections, TB, syphilis, toxemia, asthma, hepatitis, diabetes, gangrene, pneumonia, and other conditions.”⁶⁴ The court denied the injunction holding that the statements constituted reasonably

⁵⁸ *Id.*

⁵⁹ 378 F Supp 210 (DNJ 1974)

⁶⁰ *Id.* at 218.

⁶¹ *Id.* at 213.

⁶² *Id.* at 211.

⁶³ 262 F Supp 728 (D Conn 1967).

⁶⁴ *Id.* at 729-30.

factual statements of the parties claims and of the claims made about the device that were made within the authority of section 375(b).⁶⁵ The court further stated that the statements “reflect[ed] a commendable performance by the FDA of a public duty imposed by Congress in disseminating information.”⁶⁶

⁶⁵*Id.* at 729-30.

⁶⁶*Id.* at 730.

Establishing Link between Publicity and Resulting Harm

Another hurdle faced by the plaintiffs may be establishing a causal link between the publicity and the resulting harm. In *California Cannery & Growers v. United States*,⁶⁷ a fruit growers association sued the FDA to recover losses they alleged resulted from statements made by the FDA during a October 1969 press conference.⁶⁸ During the press conference the then HEW secretary announced that he was ordering cyclamate, an artificial sweetener, be removed from the list of substances “generally recognized as safe [GRAS] for use in foods.”⁶⁹ Additionally, the then FDA Commissioner released a statement concurring in the Secretary’s instructions and announcing

⁶⁷9 Cl. Ct. 774; 1986 U.S. Cl. Ct. LEXIS 882 (1986).

⁶⁸*Id.* at 776.

⁶⁹*Id.* at 777. The Secretary further stated in part:

Recent experiments conducted on laboratory animals disclosed the presence of malignant bladder tumors after an animal had been subjected to strong dose levels of cyclamate.

⁷⁰*Id.* at 778.

⁷¹*Id.* at 784.

⁷²*Id.*

Adverse Publicity and Pretrial Publicity

Even in cases where the plaintiffs do not recover, FDA publicity may still be found to constitute prejudicial pretrial publicity. In *United States v Abbott Labs, Inc.*,⁷³ the defendant laboratories were indicted for introducing into commerce adulterated and misbranded intravenous solution drugs. Hours after the indictment was handed down, the FDA issued a press release stating that 50 deaths had been attributed to defendants' intravenous solutions.⁷⁴ The Fourth Circuit held that FDA statements with was prejudicial and highly inflammatory.⁷⁵ Although the court failed to dismiss the indictment on the grounds that the publicity precluded the defendants right to a fair trial,⁷⁶ the court nonetheless indicated its "strongest disapproval that highly placed legal officers would make a statement of this important with regard to a pending criminal prosecution and even more so that FDA...would issue a press release containing such prejudicial material."⁷⁷

Recommendations

Because plaintiffs have been largely unsuccessful in obtaining compensation for losses due to FDA publicity, standards should be created that both recognize the legitimate interests of targeted companies but that that do not hamper the FDA's authority to utilize its publicity power appropriately. Specifically, be standards should created that address the issue of notice to the company, retraction/correction of inaccurate publicity, format of the publication, and publication involving judicial or administrative proceedings. Guidance for creating these standards can be found in three sources –the Administrative Conference's ("Conference") recommendations regarding agency use of adverse publicity,⁷⁸ the FDA's statement regarding its publicity policy⁷⁹, and other agency statutes.

Notice

At a minimum, the FDA should be required to notify the publicity's target of its intention of issuing the publicity. The Conference recommended that "[a]ny respondent or prospective respondent in an agency proceeding shall, if practicable and consistent with the nature of the proceeding, be given advance notice of information to be released about the proceeding and a reasonable opportunity to prepare in advance a response to the information released."⁸⁰

Even with a notice requirement, the FDA should still be allowed to discretion to determine when providing

⁷⁸See Adverse Agency Publicity, 1 C.F.R. s 305.73-1 (1973); see also Release of Adverse Information to the News Media, 45 C.F.R. 17(1976).

⁷⁹See Administrative Practices and Procedures: Publicity Policy, 42 F.R. 12436 (March 4, 1977).

⁸⁰See 45 CFR 17.6; *See also*, James T. O'Reilly, Federal Information Disclosure, 2d., FEDINFO §25:02(advocating for a notice requirement similar to the one found in the Toxic Substances Control Act, 15 U.S.C. § 2613(c)(2), which has a 30 days normal and 24 hours minimum notice requirement."

notice would compromise public safety. This is reflected in the Toxic Substance Control Act which requires the agency to “notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce” prior to publicizing confidential data about the company.⁸¹ The statute provides an exception to this notice requirement if the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.⁸²

Similarly, the Consumer Protection Safety Commission (CPSC) is statutorily required to “notify and provide a summary of the information to [the targeted company] if the manner in which such consumer product is to be designated or described in such information will permit the public to ascertain readily the identity of such [company], and shall provide [the company] with a reasonable opportunity to submit comments to the Commission.”⁸³ The statute requires 30 days notice but permits lesser notice if the agency deems that such notice is needed in the interests of public health and safety.⁸⁴ The statute further provides that the agency “shall take reasonable steps to assure...that information from which the identity of such manufacturer or private labeler may be readily ascertained is accurate, and that such disclosure is fair in the circumstances and reasonably related to effectuating the purposes of this Act.”⁸⁵ Also, if a company challenges the accuracy of information the agency intends to disclose, but disagrees, the agency must notify the company of its intention to publicize the information within 10 days of the agency receiving notification of the alleged inaccuracy.⁸⁶ Further the agency must, at the company’s request, “include with the disclosure any comments or other information or a summary thereof submitted by such manufacturer or private labeler.”⁸⁷

⁸¹15 U.S.C. § 2613(c)(2)(A)

⁸²15 U.S.C. § 2613(c)(B)(i)

⁸³15 U.S.C. § 2055(b)(1)

⁸⁴*Id.*

⁸⁵*Id.*

⁸⁶*Id.* § 2055(b)(2)

⁸⁷*Id.*

The FDA conceded the appropriateness of providing companies with notice of intended adverse publicity. It stated, however, that it would only notify the company of the subject of the intended publicity without providing the company with the full text.⁸⁸ The Agency noted that it would not provide advance notice of proposed rule making or initiation of agency action.

Correction of Inaccurate Publicity

The FDA should be required to issue corrective or retroactive publicity once it learns of the inaccuracy of previously published information.⁸⁹ The Conference recommended that in the event the information contained in the publicity is “erroneous or misleading and any person named therein requests a retraction or correction, the agency should issue the retraction or correction in the same manner (or as close thereto as feasible) as that by which the original publicity was disseminated.”⁹⁰ Although corrections and retractions may prove ineffective at undoing the harm of inaccurate publicity, as was seen in the cranberry crisis, they may potentially assistance companies in their efforts to recover from the effects of inaccurate publicity. The public may trust corrective information from the company if it accompanies FDA issued corrective information. The FDA’s proposed regulations recognized the need for issuing corrections and retractions.

Format of the Publication

⁸⁸ See Administrative Practices and Procedures, *supra*, note 79.

⁸⁹ The FDA has done so both voluntarily, for example in the cranberry scare discussed above, and as a result of court order. See, e.g., *United States v. International Medication Sys*, No. 73-626-WPG (C.D. Cal. 1973). Here the. The FDA sent letters to approximately 7,000 hospitals warning the hospitals that the sterility of some of IMS’s products were compromised and presented a “potential hazard to the public health.” The court found that the FDA violated its statutory authority by sending the letters and ordered the FDA to issue a subsequent letter to the same recipients informing them of the court’s ruling and that the company was found to not be guilty of violating good manufacturing practices “to the extent that its products represent a potential hazard to the public health.”

⁹⁰ 1.C.F.R. 305.73-1

The Conference also recommended the publicity should be “factual in content and accurate in description” and that the agency should avoid the use of disparaging terminology.”⁹¹ This requirement may have prevented the FDA from using terms such as “quackery” in *Ajay Nutrition*. In its proposed regulations, the FDA stated that it believes “there’s no way [disparaging] terminology can be entirely avoided” when the publicity is issued to warn the public of a public health threat or to report on an FDA action regarding the product. The agency conceded, however, that it should avoid the use of “personally disparaging critical remarks not required in reporting the facts of a situation.”⁹² Further, it boldly stated that it will “continue to seek publicity, when appropriate, even if there is the possibility that the information may be ignored, misinterpreted, oversimplified, overstated, or misunderstood by the media or by the public. . .”⁹³

The FDA should identify whether the information is proven or alleged. This could be done conspicuously perhaps in the form of a disclaimer.⁹⁴ Doing so may help the public make more informed choices regarding how to respond to the publicity.

⁹¹ *Id.*

⁹² *See* Administrative Practices and Procedures, *supra*, note 79.

⁹³ *Id.*

⁹⁴ *See* O’Reilly, *supra*, note 79 (quoting *FTC v. Cinderella Career & Finishing Schools, Inc.* 4040 F2d 1308, 1316 (DC. Cir. 1968)) (stating that the FTC attaches a disclaimer to its announced complaints which states that “[t]he issuance of a complaint does not indicate or reflect any adjudication of the matters charged”).

Adjudications

The Conference outlined criteria for the release of adverse publicity related to judicial or administrative proceedings.⁹⁵ It recommends that the agency should prominently disclose when adverse information contains allegations subject to agency adjudication. Further, respondents to the proceeding, to the extent practicable, should be given advance notice of the publicity and a “reasonable opportunity to prepare in advance a response to such publicity.”

For one, adverse publicity should be issued “[w]here the [agency]... determines that there is a significant risk that the public health or safety may be impaired or substantial economic harm may occur unless the public is notified immediately...”⁹⁶ The Conference further recommends that where “public harm can be avoided by immediate discontinuance of an offending practice, a respondent shall be allowed an opportunity, where feasible, to cease the practice...in lieu of release of adverse information by the agency.”⁹⁷ Secondly, use of publicity should be limited to circumstances where doing so is required to notify parties who would be interested or affected by the proceeding.⁹⁸ Thirdly, the Conference recommends that information regarding agency action is already publicly available through non-Agency means and “is likely to result in media publicity,” the agency should only issue adverse publicity to the extent needed to “to foster agency efficiency, public understanding, or the accuracy of news coverage.”⁹⁹

The FDA, in its proposed regulations, defended its use of adverse publicity that may be prejudicial in an official proceeding. The agency believes that it “must risk the dismissal of a prosecution because of the

⁹⁵45 CFR 17.4

⁹⁶*Id.*

⁹⁷*Id.*

⁹⁸*Id.*

⁹⁹*Id.*

impact of publicity, rather than fail to issue a warning that [it] believes is needed to protect the public.”¹⁰⁰

¹⁰⁰*See* Administrative Practices and Procedures, *supra*, note 79.

Conclusion

During a congressional hearing conducted in the aftermath of the cranberry crisis, the HEW Secretary defended the FDA's actions by stating, "a responsible government...cannot fail to place at the top of its list of priorities the health of all the people even though by doing so it may be or may appear to be acting against the economic interests of a segment of our society...The innocent consumer should not be made the victim...in order to protect the innocent producer."¹⁰¹ The Secretary's statements illustrate the obvious tension between the FDA's legitimate efforts to protect the public through its use of publicity and the interests of companies who may be the target of the publicity. There are no easy answers to ways to resolve this tension, however, the FDA should take guidance from the Administrative Conference recommendations and other agency statutes that prescribe guidelines for the use of adverse publicity. Because the plaintiffs have limited judicial recourse to recover losses due to inaccurate adverse publicity, and because this publicity could be fatal to the company, regulations should be created to ensure for the accuracy of the information and adequate notice to the company. The FDA's strong stance on its use of adverse publicity, as outlined in its proposed regulations, is necessary for the agency to carry out its duty to the public. Consumers need to know that the agency entrusted with the responsibility of ensuring the safety of the foods they eat, the medications and medical devices on which they rely, and the cosmetics they use will not cave in to the pressures from the companies affected by its publicity policies.

¹⁰¹Hearings before House Committee on Interstate and Foreign Commerce, 86th Cong. 2d Sess. H.R. 7624 168-71; The Cranberry Scare and Cabinet Immunity, 16 Food Drug Cos LJ 209 (1961)